REMARKS

Status of the Application

Claims 1-40 were originally pending in the application. In the Office Action dated April 26, 2004, the Examiner rejected claims 1-40. No claims have been withdrawn or canceled; therefore, claims 1-40 remain at issue in the current application.

Oath/Declaration

The Examiner has deemed the Declaration submitted in connection with the present Application to be defective because he claims the residential street address, Inventor's Signature and Date of signature for Zakir S. Murtaza is obsecure and unreadable. Applicants respectfully request reconsideration of this objection. The original declaration is legible. As such, it is believed the copy submitted to the PTO may have been blurred. Submitted herewith is a clean copy of the same declaration. Applicants submit all information is readable, thus overcoming the objection. If there is still concern, the Examiner is invited to advise Applicants.

Specification

The Examiner has objected to the Brief Description of the Drawings due to certain informalities. The specification has been amended to correct the informalities noted in the Office Action.

Rejection of Claims Under 35 U.S.C. §112

The Examiner rejected Claims 1, 4-5, 11, 16, 18, 23, 28, 34, 35, and 40 under 35 U.S.C. §112 as being indefinite. By this Response, Claims 1, 4-5, 11, 16, 18, 23, 28, 34, 35, and 40 have been amended to address the Examiner's rejections.

With respect to claims 5 and 23, the chemical name "polyoxyethylene (10) isooctylphenyl ether" is the proper name for the claimed compound as evidenced by the attached document (see Appendix A). Accordingly, any person skilled in the art would understand the reference to be proper. Therefore no amendment is required.

In view of the foregoing reasons and amendments, Applicants respectfully request Examiner to withdraw the rejection of Claims 1, 4-5, 11, 16, 18, 23, 28, 34, 35, and 40 under 35 U.S.C. §112.

Rejection of Claims Under 35 U.S.C. §103

Claims 1-3, 7-17, 19, 27, 28, 32-36, 40 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Schmerr et al., US 6,150,172, in view of Sundrehagen, WO 00/36418, and further in view of Pugia et al., US 5,846,754. Applicants respectfully request reconsideration of this rejection because Applicants' invention is not obvious in view of these references.

In order to support a conclusion that a claim is directed to obvious subject matter, the cited references must impliedly suggest the invention described by the claim, or the Examiner must present a convincing line of reasoning as to why an artisan would have found the claimed invention obvious in light of the teachings of the cited references. See *Ex Parte Clapp, 227 U.S.P.Q.* 972 (PTO Bd. App. 1985). "[T]he mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification." *In re Laskowski et. al.*, 10 U.S.P.Q. 2d 1397, 1398, (Fed. Cir. 1989), citing, *In re Gordon*, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). In discussing the mandate of 35 U.S.C. §103, the Federal Circuit holds "it is the invention as a whole that must be considered in obviousness determinations. The invention as a whole embraces the structure, its properties and the problem it solves." [Emphasis added]. *In re Wright*, 6 U.S.P.Q. 2d 1959 (Fed. Cir. 1988). It is not enough to just find components in the prior art.

On that point, the Federal Circuit has noted,

> "it is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious . . . . [o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention."

In re Fitch, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992).

Unless the references suggest the particular combination themselves, they cannot show the actual invention was obvious. *In re Mahurkar* Patent Litigation, 831 F.Supp. 1354, 1374, 28 USPQ2d 1801, 1817 (N.D. Ill. 1993). The decomposition of an invention "into its constituent elements, finding each element in the prior art, and then claiming that it is easy to reassemble these elements into the invention, is a forbidden ex post analysis." *Id.* Thus the modification of Schmerr et al. in view of Sundrehagen and Pugia et al. in a manner that apparently reconstructs Applicants' invention is improper and insufficient to present a *prime facie* case of obviousness. Accordingly, the Applicants traverse the Examiner's rejection of the pending claims. Reconsideration and withdrawal of all rejections in light of the amendments and remarks is respectfully requested.

Schmerr et al. disclose a method for extracting prion protein from a biological material. More specifically, Schmerr et al. discloses a method of extracting abnormal prion protein using organic solvents followed by generally detecting the presence of prion protein using known immunoassays.

Schmerr et al. neither teaches nor suggests Applicants' invention. Applicants describe and claim a rapid diagnostic assaying method for detecting the pathogenic form of prion in biological fluids and tissues. Applicants' invention differs from the Schmerr et al. reference in several aspects. First, Applicants' claims are directed to homogenizing a biological sample with a buffer. This is done in order to optimize the extraction of prion protein into the buffer medium. (Spec. p. 9, ll. 3-4). Applicants' invention uses a buffer without organic solvents (Spec. p. 9, ll. 9-24). Schmerr et al. discloses using an organic extraction solvent for extracting the prion protein (col. 6, ll. 22-35). Furthermore, Applicants' invention teach a method of isolating the

pathogenic prion by digesting substantially all of the non-pathogenic protein using immobilized proteinase-K on a digestive pad of the test device (Spec. p. 13, ll. 12-25 and p. 14, ll. 1-6). As mentioned above, unlike Applicants' invention, Schmerr et al. teaches a method of isolating the pathogenic prion using organic extracting solvents. (col. 6, ll. 22-35).

Another improvement Applicants' invention discloses and claims is the ability to allow substantially real-time reading of the results on the prion assay test device, so that the results are available almost instantaneously (Spec. p. 22, ll. 7-8). Depending on the amount of normal prion protein to be denatured, test results can be available from about 0.5 to about 20 minutes (Spec. p. 22, ll. 13-14). Schmerr et al. does not disclose a method for extracting prion protein having instantaneous results.

Furthermore, Applicants specifically disclose and claim methods using a test device used for detecting the pathogenic prion. Specifically, Applicants disclose use of an immunochromatographic membrane test device for rapidly detecting prion proteins. Schmerr et al. generally discloses different immunoassays that are available for detecting abnormal prion protein, but Schmerr et al. fails to teach or suggest any specifics of the immunochromatographic membrane test device. For the reasons stated above, there is evidence in the record showing that Applicants' invention is different than the method of the cited reference. Thus, Applicants' invention is not obvious in view of Schmerr et al.. Reconsideration and withdrawal of all rejections based on Schmerr et al. are respectfully requested.

Sundrehagen discloses a test device for detecting and quantifying the content of analyte in a sample using a dipstick assay for detecting and quantifying analyte forms having carbohydrate-containing and carbohydrate-free variants. As stated in the Office Action,

"Sundrehagen differs from the instant invention in failing to teach proteinase-K immobilized in the test device." Applicants' invention discloses a method for essentially pre-treating biological material that uses proteinase-K to digest the non-pathogenic prion protein on a support external to the test strip (Spec. p. 17, ll. 16-17). Sundrehagen neither teaches nor suggests pre-treating the biological sample with proteinase-K to digest the non-pathogenic prion protein.

Notably, Sundrehagen does not teach or suggest a test device for detecting prion proteins. Instead, Sundrehagen teaches detecting and quantifying analyte forms having carbohydrate-containing and carbohydrate-free variants. Furthermore, Sundrehagen uses "lectins" to remove non-target analyte variants. Lectin is a binding ligand that has binding affinity for non-target analyte. Sundrehagen utilizes this mechanism for separating a non-binding fraction containing the target analyte - a carbohydrate-free variant. The lectin removes the carbohydrate-containing portion of the sample. The analyte in this case is carbohydrate-free transferin. Applicant's invention utilizes an enzymatic digestion, with proteinase-K, to remove the non-pathogenic prion protein. Contrary to the Examiner's assertions in the Office Action, there is ample evidence in the record showing that Applicants' invention is different from Sundrehagen Thus, Applicants' invention is not obvious in view of Sundrehagen

Pugia et al. disclose a method for end-pointing a determination of an enzyme, or enzyme substrate, in a sample by utilizing a protease to inactivate an enzyme to provide an end-point for the enzyme catalyzed reaction. Applicants' do not use a protease for ending an enzymatic reaction. Rather Applicants' use proteinase-K enzyme, a protease, to remove substantially all of the non-pathogenic prion protein or interfering components (Spec. p. 11, ll. 7-9). Pugia et al. does not teach or suggest using protease for removing non-pathogenic prion protein. Clearly,

Pugia et al. does not teach or suggest Applicants' invention. The Examiner has also stated in the Office Action that "Pugia et al. teaches that it is known in the art to immobilize enzymes to a test device prior to the addition of sample." However, Applicant respectfully disagrees with this assertion. The Examiner has provided no specific evidence to support this contention. Applicants could find no teaching or suggestion of this feature.

It is clear that Applicants' invention is distinct from the above references. Further, there is simply no motivation to combine these references, which individually teach completely different methods from one another, as well as from Applicants' product. It has been acknowledged that Schmerr et al. fails to teach the specifics of the immunochromatographic membrane, and Schmerr et al. and Sundrehagen fail to teach proteinase-K immobilized in the test device. Therefore, it does not follow that one skilled in the art would combine the teaching of Schmerr et al., Sundrehagen, or Pugia et al., to arrive at Applicants' invention. This simply cannot be done properly.

Claims 6, 18, 20, 21, 29, 30, 38, and 39 were rejected under 35 U.S.C. §103(a) as being unpatentable over Schmerr et al., US 6,150,172, in view of Sundrehagen, WO 00/36418, and further in view of Pugia et al., US 5,846,754. Claims 6, 18, 20, 21, 29, 30, 38, and 39 ultimately depend from Claims 1-3, 7-17, 19, 27, 28, 32-36, 40, and add further limitations thereon. Accordingly, these claims are likewise not obvious in view Schmerr et al., Sundrehagen, and Pugia et al.. Applicants respectfully requests that the rejection under §103(a) be withdrawn with respect to these claims also.

Conclusion

In view of the amendments and arguments presented above, Applicant respectfully submits that Claims 1-40 are now in condition for allowance, and such action to this end is respectfully requested. The Examiner is authorized to call the undersigned counsel if it would expedite the process of this application.

Respectfully submitted,

Dated: October 26, 2004 By: 

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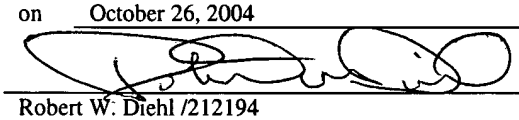

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F.W.:
CAS #: 9036-19-5
DOT: NR
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Specific Gravity: 1.070

Description

9036-19-5, Polyoxyethylene(10) isooctylphenyl ether. n in formula is about 10

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APPENDIX A